

Patent Claims

1. Film-shaped administration form for transmucosal administration of active substances, characterized in that
 - the said administration form is a dried film, and
 - that the pH value of the base mass which is used for the production of said administration form and which comprises a solvent or a mixture of solvents, at least one matrix-forming polymer and at least one active substance was, during the production thereof, approximated or adapted to the physiological pH value of the mucosa to which the administration form is to be applied, and
 - that the said active substance(s) is/are selected from the group consisting of pharmaceutically active substances and aroma substances.

2. Administration form according to claim 1, characterized in that water is used as the solvent or at least as one of the solvents of the mixture of solvents.

3. Administration form according to claim 1 or 2, characterized in that the matrix-forming polymer is selected from the group consisting of polyvinyl alcohol; cellulose derivatives such as hydroxypropyl methyl cellulose, hydroxypropyl cellulose, sodium carboxymethyl cellulose, methyl cellulose, hydroxyethyl cellulose and hydroxypropyl ethyl cellulose, carboxymethyl cellulose, as well as ethyl or propyl cellulose; starch and starch derivatives; gelatine; polyvinyl pyrrolidones; gum arabic; pullulan; acrylates; dextran; polyacrylic acid; polyacrylates; polyethylene oxide polymers; polyacrylamides; polyethylene glycol; collagen; alginates; pectins; tragacanth; chitosan; alginic acid; arabinogalactan; galactomannan; agar-agar; agarose; carrageenan; and natural gums.

BEST AVAILABLE COPY

4. Administration form according to any one of the preceding claims, characterized in that the polymer portion is 5 to 95%-wt., preferably 15 to 75%-wt, relative to the dry mass of the administration form.

5. Administration form according to any one of the preceding claims, characterized in that the content of pharmaceutically active substance is 0.1 to 50%-wt., preferably 0.5 to 20%-wt., relative to the dry mass of the administration form.

6. Administration form according to any one of the preceding claims, characterized in that the content of aroma substance is 0.1 to 20%-wt., preferably 1 to 10%-wt., relative to the dry mass of the administration form.

7. Administration form according to any one of the preceding claims, characterized in that the pH value of the base mass was adjusted to a value in the range between 5 and 9, preferably in the range between 6 and 8.5, and particularly preferably in the range between 6.5 and 8.

8. Administration form according to any one of the preceding claims, characterized in that the pH value was adjusted by means of sodium hydroxide, potassium hydroxide, ammonia, hydrochloric acid, phosphoric acid, or a buffer system, such as, for example, a phosphate buffer.

9. Administration form according to any one of the preceding claims, characterized in that it is mucoadhesive.

10. Administration form according to any one of the preceding claims, characterized in that it is disintegratable.

11. Administration form according to claim 10, characterized in that it has become disintegrated within 15 min, preferably within 3 min, and particularly preferably within 60 s, after having been introduced in an aqueous medium.

12. Administration form according to any one of the preceding claims, characterized in that it is multilayered.

13. Administration form according to any one of the preceding claims, characterized in that it contains one or more adjuvants from the group comprising filling agents, colourants, flavourings, aroma substances, fragrant substances, emulsifiers, plasticizers, sweeteners, preservatives, permeation-enhancing substances, and antioxidants.

14. Administration form according to claim 13, characterized in that the portion of adjuvants amounts to up to 30%-wt., preferably 1 to 20%-wt., relative to the dry mass of the administration form.

15. Use of the administration form according to any one of the preceding claims for oral, gingival, vaginal or rectal application.

16. Process for the production of a film-shaped administration form for transmucosal administration of active substances, comprising:

- preparing a base mass comprising a solvent or a mixture of solvents, at least one matrix-forming polymer and at least one active substance,
- approximating or adapting the pH value of the base mass to the physiological pH value of the mucous membrane to which the administration form is to be applied,
- extruding the mass,
- drying the moist film, and

- singularizing the administration form; the said active substance(s) being selected from the group consisting of pharmaceutically active substances and aroma substances.

17. Process according to claim 16, characterized in that water is used as the solvent or at least as one of the solvents of the mixture of solvents.

18. Process according to claim 16 or 17, characterized in that the pH value of the base mass is adjusted to a value in the range between 5 and 9, preferably in the range between 6 and 8.5, and particularly preferably in the range between 6.5 and 8.

19. Process according to any one of claims 16 to 18, characterized in that adjustment of the pH value is accomplished by means of sodium hydroxide, potassium hydroxide, ammonia, hydrochloric acid, phosphoric acid or a buffer system such as, for example, a phosphate buffer.

BEST AVAILABLE COPY